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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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32

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/020,716

Applicant(s)

JUNG ET AL.

Examiner

Amy Nelson

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/9/00, 02/05/01 & 04/16/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 30.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claim Objections

1. Claim 94 is objected to because of the following informalities:

At line 3, "and" should be changed to --an--.

Claim Rejections - 35 USC § 112

2. Claims 75-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official action mailed 5/18/99 as applied to Claims 1-21, the Official action mailed 11/22/99 as applied to Claims 6, 7, 14-17, and 21-35, the Official action mailed 4/21/00 as applied to Claims 36-56, and the Official action mailed 8/9/00 as applied to Claims 57-74. Applicant has presented no additional arguments in the responses filed 11/9/00, 2/5/01, or 4/16/01, and hence the rejection is maintained.

3. Claims 75-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed

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cereal plant seed) comprising the modified hordothionin gene of SEQ ID NO:2 (HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official action mailed 5/18/99 as applied to Claims 1-21, the Official action mailed 11/22/99 as applied to Claims 6, 7, 14-17, and 21-35, the Official action mailed 4/21/00 as applied to Claims 36-56, and the Official action mailed 8/9/00 as applied to Claims 57-74. Applicant has presented no additional arguments in the responses filed 11/9/00, 2/5/01, or 4/16/01, and hence the rejection is maintained.

4. Claims 75-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 75, line 1, the phrase "nutritional value" is indefinite because it is not clear what is encompassed by the phrase. Also, the phrase is not consistent with the method steps directed to increasing lysine or sulfur-containing amino acids in seed. It is recommended that the phrase be changed to --lysine or sulfur-containing amino acid content--.

At Claim 75, line 4, the phrase "high lysine content" is indefinite because "high" is a relative term, and hence it is not known what is encompassed by the phrase.

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At Claim 75, line 4, the phrase "high sulfur content" is indefinite because "high" is a relative term, and hence it is not known what is encompassed by the phrase.

At Claim 75, line 5, the phrase "modified seed storage protein of same" is indefinite. There are many different types of modifications and hence it is not clear what is encompassed by "modified." Also, "of same" is unclear. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 75, line 6, "the transformed cell" lacks proper antecedent basis.

At Claims 76 and 77, line 1, "the transformed plant seed" lacks proper antecedent basis.

At Claim 78, line 2, the phrase "modified proteins of same" is indefinite. There are many different types of modifications and hence it is not clear what is encompassed by "modified." Also, "of same" is unclear. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

Claim 79 is improperly dependent on Claim 75. Amendment of Claim 75 to recite --A method of producing a transformed cereal plant seed-- would obviate this rejection.

At Claims 81 and 82, line 1, "The transformed seed of Claim 80" lacks proper antecedent basis and should be changed to --The transformed cereal plant seed of Claim 80--.

At Claims 81 and 82, line 1, "the transformed plant seed" lacks proper antecedent basis and should be changed to --the transformed cereal plant seed--.

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At Claim 83, line 1, "The transformed seed according to Claim 80" lacks proper antecedent basis and should be changed to --The transformed cereal plant seed of Claim 80--. Claims 84 and 85 should be amended accordingly.

At Claim 89, line 3, the phrase "modified seed storage protein" is indefinite. There are many different types of modifications and hence it is not clear what is encompassed by "modified." Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 89, line 3, the phrase "elevated level of lysine or methionine" is indefinite because "elevated" is a relative term, and hence it is not known what is encompassed by the claim. Appropriate correction to clarify the metes and bounds of the claimed invention is required.

At Claim 94, line 2, the phrase "modified seed storage protein" is indefinite. There are many different types of modifications and hence it is not clear what is encompassed by "modified." Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 94, line 4, the term "compound" is inconsistent with "protein" at line 2. The term should be changed to --protein--.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 75-94 are rejected under 35 U.S.C. 102(e) as being anticipated by Falco *et al.* (U.S. Patent 5,773,691).

The claims are indefinite for the reasons discussed above. In particular, the phrase "modified proteins of same" is indefinite and reads on essentially any protein.

Falco discloses transformed plant seed, including corn, and feed produced from said seed, having enhanced lysine content by introduction of vectors encoding lysine insensitive enzymes or lysine-rich proteins (Abstract; Col. 1, lines 18-30; Col. 6, line 22 - Col. 7, line 44; Col. 9, line 38 - Col. 10, line 37; Col. 30, line 15 - Col. 31, line 62; Examples 22, 23, 25). In particular, Falco teaches said transformed plants wherein the increases in lysine are 10-400% (Col. 6, lines 65-66), and Falco teaches use of an endosperm-specific promoter, including the zein promoter (Col. 19, lines 40-55), and the use of a gene encoding 2S albumin from Brazil nut (Col. 2, lines 10-20). Hence, all of the claim limitations have been previously disclosed by Falco.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 75-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao *et al.* (U.S. Patent 5,885,802) in view of Applicant's Admission.

The claims are indefinite for the reasons discussed above. In particular, the phrase "modified proteins of same" is indefinite and reads on essentially any protein.

Rao teaches transformed seed with elevated levels of methionine, a sulfur-containing amino acid, and feed derived therefrom, by expression of a mutant barley hordothionin gene with methionine amino acid substitutions (Abstract; Col. 2, lines 19-29; Col. 2, line 66 - Col. 3, line 8). Specifically, Rao teaches transformed cereal crop seed, including maize, wheat, rice or sorghum (Col. 3, lines 55-58). Although Rao does not specifically recite the amount of increase in methionine in transformed seed, the seed of Rao are believed to be encompassed by the claimed invention, absent evidence to the contrary.

Rao does not specifically teach use of an endosperm-specific promoter.

Applicant admits that endosperm-specific promoters, including the zein promoter and the waxy promoter, were well known in the art at the time of Applicant's invention (Specification, p. 18, lines 7-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao to substitute an endosperm-specific promoter, as admitted by Applicant to have been known in the art, for the constitutive promoter,

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because the invention was clearly directed to modification of seed tissue, and especially endosperm. The different promoters are functional equivalents, and it would have been obvious to substitute one functional equivalent for another. Hordothionine is a seed protein and hence expression in the seed (the major portion of which is endosperm) would be expected to be successful. Also, it was well known in the art that increased nutritional value of seeds was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Rao.

9. Claims 75-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao *et al.* (U.S. Patent 5,990,389) in view of Applicant's Admission.

The claims are indefinite for the reasons discussed above. In particular, the phrase "modified proteins of same" is indefinite and reads on essentially any protein.

Rao teaches transformed seed with elevated levels of lysine, and feed derived therefrom, by expression of a mutant barley hordothionin gene with lysine amino acid substitutions (Abstract; Col. 1, line 66 - Col. 2, line 4; Col. 3, lines 1-26). Specifically, Rao teaches transformed cereal crop seed, including maize, wheat, rice or sorghum (Col. 4, lines 47-50). Although Rao does not specifically recite the amount of increase in lysine in transformed seed, the seed of Rao are believed to be encompassed by the claimed invention, absent evidence to the contrary.

Rao does not specifically teach use of an endosperm-specific promoter.

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Applicant admits that endosperm-specific promoters, including the zein promoter and the waxy promoter, were well known in the art at the time of Applicant's invention (Specification, p. 18, lines 7-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao to substitute an endosperm-specific promoter, as admitted by Applicant to have been known in the art, for the constitutive promoter, because the invention was clearly directed to modification of seed tissue, and especially endosperm. The different promoters are functional equivalents, and it would have been obvious to substitute one functional equivalent for another. Hordothionine is a seed protein and hence expression in the seed (the major portion of which is endosperm) would be expected to be successful. Also, it was well known in the art that increased nutritional value of seeds was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Rao.

10. Claims 75-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,811,654) in view of Applicant's Admission. This rejection is repeated for the reasons of record as set forth in the Official action mailed 8/9/00 as applied to Claims 57-74, and the Official action mailed 4/21/00 as applied to Claims 36-56. The rejection is restated below.

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Applicant has presented no additional arguments in the responses filed 11/9/00, 2/5/01, or 4/16/01, and hence the rejection is maintained.

The claimed invention is indefinite for the reasons discussed *supra*.

Jaynes teaches transformed plants with elevated levels of methionine, lysine and/or threonine by expression of a modified gene with methionine, lysine and/or threonine amino acid substitutions (Abstract; Col. 5, lines 9-14, 29-40; Col. 11, line 24 - Col. 16, line 28; Examples 13-16). Specifically, Jaynes teaches transformed cereal crops, including rice and maize (Col. 6, lines 22-24; Col. 11, lines 35-38; Examples 11 and 12), and seed of the transformed plants (Col. 15, lines 21-23). Jaynes teaches increased amino acid levels of 25-60% (Col. 5, lines 29-33), and Jaynes teaches a modified zein gene (Col. 13, lines 29-32).

Jaynes does not teach specific expression of the modified gene in the endosperm tissue.

Applicant admits that endosperm-specific promoters, including the zein promoter and the waxy promoter, were well known in the art at the time of Applicant's invention (Specification, p. 18, lines 7-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Jaynes to direct expression of the modified gene to the endosperm by expressing it behind an endosperm-specific promoter as admitted by Applicant to have been well known in the art. It was well known in the art that increased nutritional value of seeds (the major portion of which is endosperm tissue) was particularly

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desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Jaynes.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

June 24, 2001